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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,047	11/22/2000	Nilgun E. Tumer	OCIRS 3.3-060 CONT	2314

530 7590 03/11/2004

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/721,047	Applicant(s) TUMER ET AL.	
	Examiner Georgia L. Helmer	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 13-17, 19-31 and 33-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12, 18 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 22 December 2003.
2. Claims 1-37 are pending. Applicant has amended claim 18. Claims 1-5, 12, 18, and 32 are examined in the instant Action. Claims 6-11, 13-17, 19-31 and 33-37 are withdrawn as being drawn to nonelected inventions. This action is made FINAL necessitated by Applicant's amendment.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112-second***

5. Claims 1, 2, 4, 5, 12 and 18 remain rejected under 35 U.S.C. 112-2<sup>nd</sup>, for reasons of record.

Claim 1 was rejected as indefinite in that it recites a sequence encoding a "PAPII protein", and Applicant says (p 7) that "PAPII protein" also includes mutants or analogues of the wild-type polypeptide such as fragments and amino acid substitutions and /or deletions. Defined this way, PAPII protein is indefinite; it can means many different things and is unclear because the metes and bounds of such a claim cannot be defined.

Applicant traverses, stating primarily that the definition of this recitation is not confined to page 7, rather it is set for the in the disclosure beginning on page 5 through

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page 9, in terms of its structure and function. Applicant further alleges that the claim recitation at issue embraces "mutants or analogs", thus making the claim broader rather than narrower, and does not make the claim indefinite. Applicant states that persons skilled in the art would readily understand the meaning of the term in the present context in which it is used. Applicant's traversal has been considered and is unpersuasive because Applicant is arguing limitations not present in the claim.

Claim 1, drawn to a recombinant plant cell or plant thereof containing a DNA molecule comprising a sequence encoding a PAP II protein, remains rejected for reasons of record. This claim is ambiguous: it can be a *Pytolacca Americana* cell transformed with a heterologous DNA, or any plant cell comprising a heterologous DNA encoding any PAP II protein. Dependent claims 2, 4, 5, and 12, also remain rejected.

In claim 4, the recited "PAPII (1-285)" needs a SEQ ID NO: inserted into the claims as an identifier. Applicant traverses saying primarily that the claim recitation is clearly defined on page 5, lines 30-31. Applicant's traversal is unpersuasive. The definition of PAP II on page 5 is not limited.

In claim 5, a "mutant" PAPII is unclear because the metes and bounds of such a claim cannot be defined. A "mutant" can encompass deletions, substitutions, additions, rearrangements, replacements, and combinations thereof. Applicant traverses, stating primarily that this claim recitation would be clear and definite to person in the art. Applicant's traversal is unpersuasive. The activity and the structure of the claimed protein is lacking.

Claims 5 and 18, reciting an "intact" catalytic active site amino acid residue, are unclear. What is "intact"? The active site? The amino acid residue? Or something else. Applicant traverses, stating primarily that "intact" is clear in that whatever deletion, substitution, etc., that mutation does not involve the E172 residue. Applicant traverses, stating primarily, ( response, page 7) with respect to the rejection of claims 5, 4, and 18 as being unclear because of the meaning of the numbers in parentheses, the specification clearly indicated that the parenthetical recitations are a shorthand notation for the specific amino acid residues for amino acid sequence contained within SEQ ID NO: 4, set forth in Table 2 of the specification. Applicant's traversal has been considered and is unpersuasive the recited sequence information of Table 2, shows at position 172, a T residue (threonine). An E (glutamate) residue is just upstream, but not at position 172.

***Claim Rejections - 35 USC § 112, first paragraph***

***Written description***

6. Claims 1-5, 12, 18, and 32 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a recombinant plant cell or part thereof containing a DNA molecule comprising a sequence encoding a PAP II protein. Applicant says (p 7) that

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"PAPII protein" also includes mutants or analogues of the wild-type polypeptide such as fragments and amino acid substitutions and /or deletions. There is no structural description, of what comprises the PAP II protein, and there is no functional requirement or description. Applicants are claiming a genus of sequences, yet there is no description of the structural features or the functional features that define the genus. Applicant traverses saying primarily that the Examiner has offered no reasoning or evidence as to why these teachings fail to provide written description support for these claims. Applicant's traversal is unpersuasive. Applicant has failed to provide the required support. Applicant should note that claims 1-2, 4, 5, 12 and 18 are not limited claims.

Claim 5 is drawn to a recombinant plant cell containing a DNA molecule comprising a sequence encoding a PAP II protein, where in the sequence encodes a "mutant PAPII protein that has intact catalytic active site amino acid residue (E172) and exhibits anti-viral and/or anti-fungal activity. There is no structural description, other than the intact E172, of what comprises the mutant PapII. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus. Applicant traverses saying primarily that the Examiner has offered no reasoning or evidence as to why these teachings fail to provide written description support for these claims. Applicant's traversal is unpersuasive. Applicant has failed to provide the required support. Applicant should note that claims 1-2, 4, 5, 12 and 18 are not limited claims.

Claim 18 is drawn to a DNA molecule comprising a sequence encoding a PAP II protein, where in the sequence encodes a PAPII protein that has intact catalytic active site amino acid residue (E172) and exhibits anti-viral and/or anti-fungal activity. There

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is no structural description, other than the intact E172, of what comprises the Pap II. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus. Applicant traverses saying primarily that the Examiner has offered no reasoning or evidence as to why these teachings fail to provide written description support for these claims. Applicant's traversal is unpersuasive. Applicant has failed to provide the required support. Applicant should note that claims 1-2, 4, 5, 12 and 18 are not limited claims.

#### Remarks

7. SEQ ID NO: 3 is known in the prior art.
8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

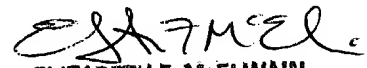
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner  
Art Group 1638  
5 March 2004

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1800